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AGOUZA SERUM AND VACCINE INST CAIRO (EGYPT)  
CHOLERA VACCINE.(U)  
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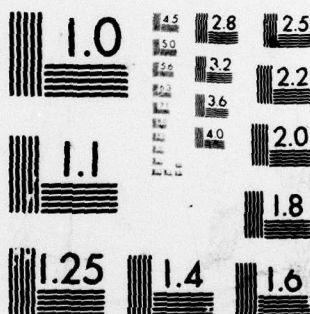
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MICROCOPY RESOLUTION TEST CHART  
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OFFICE OF NAVAL RESEARCH

Contract <sup>15</sup> N00014-74-C-0392 <sup>new</sup>

Task No. ~~136-947~~  
204-057

<sup>9</sup> ANNUAL REPORT, NO. 3 (Annual)

15 June 1976 - 14 June 1977

<sup>6</sup> Cholera Vaccines

By

<sup>10</sup> Violet Jakla/Rizk

<sup>11</sup> 14 Jun 77

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Agouza Serum and Vaccine Inst., Cairo (Egypt)

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The vaccine field trial which was carried out in a village named Ballacks in Kalyoubia Province was preceded in November and December 1975 by a house to house census after dividing the area into 4 districts. Every district was given a separate code number, the families were numbered serially within the village and individuals within each family were given a serial number. Only adults were accepted in the trial.

In continuation to the work previously mentioned in the second annual report, further progress took place both in the field and laboratory.

Field trial:

1. Serological Surveillance for vaccinees:

Four serological surveys were planned to be made on the vaccine recipients, who were all adult individuals. p.4

As serological surveys are of great value in the evaluation of an immunization program, an initial survey was carried out before embarking on our vaccine trial to provide a baseline for later evaluation of immunization. Serum samples were collected from healthy individuals in the field area which was free of cholera at the time specimens were collected before vaccination

program had begun. Later they were tested in the vibriocidal antibody titre among them.

The second survey was made 2 months after the first. The third survey was made 3 months after the first vaccine dose and 4 months after the second vaccine dose. The fourth survey was made 6 months after immunization.

a. Serum Samples:

The first samples and part of the second samples were totally collected during the second year of the research (see second annual report).

Second serum samples: 1100 samples were further collected from the volunteers to make a total of 3370.

Third serum samples: 2769 samples were collected to make a total of 2880 samples.

Fourth serum samples: 2502 samples were collected 6 months after immunization with the test vaccines and placebo.

The number of the third and fourth samples were relatively less than the first and second samples due to several factors as the fasting season (Ramadan), hot summer weather and local markets etc...

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b. Stools Samples:

Two samples of stools were taken from each of 300 individuals, the first one taken just before immunization. The second one was taken 2 weeks later. Each of those individuals had been vaccinated with one type of the vaccines used in the trials. After processing, the filtrate was stored in a deep freeze unit at -20°C until use.

2. Multiple sites of injection of the vaccine:

This was tried on 44 individuals using the phenolized vaccine only. The vaccine dose was divided into 2 halves, each half was injected simultaneously with the other into each upper arm of one individual subcutaneously to test for the effect of the use of double sites of immunization on the vibriocidal titre of this specimen compared to the titre of those immunized by injection into one site only.

3. Reactions to various types of vaccines used:

Follow up of vaccinees for side effects of the different vaccines used in the trial took place by our field team. They looked for both (1) general reactions: as anorexia, nausea, vomiting, headache, fever, rigors, arthralgia, myalgia, asthenia and (2) local reactions as redness, swelling, induration and glands.

### Laboratory work:

#### Methods:

1. Serum specimens were tested for vibriocidal antibody using the vibriocidal test which is a complement dependant test system. The microtechnique described by Benenson (1968) was adopted, using the microtiter kit with loops and pipette droppers calibrated to deliver 0.025 ml. The serum specimens were tested in double-fold dilution starting from 1:10. Geometric mean titres were calculated after assigning a titer of 1:5 to titers of less than 1:10.
2. A small ratio of the serum specimens are being tested for serum immunoglobulins by Mancini (1965) Single Radial immunodiffusion method and the test is still being carried on, results are not yet available in a good number.

#### Results:

##### Frequency of postvaccination reactions:

1. On the whole, general reactions to all vaccines used were rare; for follow up of vaccinees the field team searched for anorexia, nausea, vomiting, headache, fever, rigors, arthralgia, myalgia and asthenia, but they spotted only a few cases of fever, headache, nausea, arthralgia and one

→ case of shock which happened instantaneously after injection of the vaccine which was the formalin-inactivated formalin neutralised vaccine. Patient was resuscitated by giving him decadon and adrenaline. For percentage of general reactions see table (1).

2. A good percentage suffered ~~at~~ various degrees of local reactions, local erythema, swelling, induration and glands were looked for. The formalin-inactivated, formalin-unneutralized cholera vaccine caused more of these local reactions than the other vaccines did. Table (2) reflects the frequency of local reactions caused by the various vaccines.

Results of serological survey on 3565 healthy individuals before vaccination:

The distribution of the serum vibriocidal titer in this baseline specimen of population is shown in table (3).

The titre ranged between 0-320. About 83.5% had no measurable prevaccination vibriocidal titers, and the remaining percentage were found to have prevaccination vibriocidal titers. The history of previous vaccination against cholera was doubtful in most of the subjects and could not be relied upon. The geometric mean titre against Ogawa was found to be 5.43 and against Inaba was found to be 5.72.

N.B. Trials are proceeding to grow cholera vibrio vaccine strains on Lupinous Termis seed medium aiming at preparing a more potent cholera vaccine. These seeds are grown locally in the country.

Publications :

A paper entitled "Laboratory evaluation of the antigenicity of three chemically inactivated cholera vaccines" has been accepted for publication in the Journal of the Public Health Association, and copies will be sent as soon as available.

Another manuscript discussing the distribution of vibriocidal antibody titre among normal healthy individuals in Egypt is proceeding.

References:

1. Benenson, A. S., Saad Anisa and Mosley, W. H. Bull. Wld Hlth Org., 38:277-285, 1968
2. Mancini, G., Carbonara, A. O. and Heremans J. F. Immunochochemistry. Pergamon Press 2:235-254, 1965

TABLE 1 - FREQUENCY OF GENERAL REACTIONS TO FIELD VACCINES

Vaccine	No. Examined	Percentage General Reactions			
		Fever	Headache	Nausea	Arthralgia
1. Phenol-inactivated	329	0.3	0.9	-	-
2. Formalin-inactivated and neutralized	270	0.37	0.7	1	
3. Formalin-killed. Formalin unneutralized	262	0.7	1.5	-	0.3
4. TAB (1:5) Placebo	237	-	-	-	-

TABLE 2 - FREQUENCY OF LOCAL REACTIONS TO FIELD VACCINES

Vaccine	No. Examined	Percentage local reactions				
		Pain	Tenderness	Erythema	Swelling	Induration Glands
1. Phenol-inactivated	329	7.3	77	10.9	5.47	0.3 -
2. Formalin-inactivated and neutralized	270	8.1	75	11.8	5.18	0.3 -
3. Formalin-killed. Formalin unneutralized	262	9.9	80	20.6	9	2.6 0.3
4. TAB (1:5) Placebo	237	2.2	72.5	3.8	1.7	0.8 -

TABLE 3 - DISTRIBUTION OF VIBRIOCIDAL ANTIBODY TITRES  
AMONG 3565 CLINICALLY HEALTHY UNVACCINATED, INDIVIDUALS.

Vibriocidal Titer	No. of individuals showing serum titer against	
	Ogawa (percentage)	Inaba (percentage)
Negative	3184 (89.3%)	2976 (83.5%)
1:10	352 ( 9.9%)	524 (14.7%)
1:20	20 ( 0.56%)	43 ( 1.2%)
1:40	5 ( 0.14%)	12 ( 0.34%)
1:80	2 ( 0.06%)	8 ( 0.22%)
1:160	2 ( 0.06%)	1 ( .03%)
1:320	-	1 ( .03%)
Total Number	3565	3565

TABLE 4 - GEOMETRIC MEAN VIBRIOCIDAL TITRE  
IN 3565 CLINICALLY HEALTHY UNVACCINATED INDIVIDUALS

G.M.V.T.	G.M.V.T.
Against Ogawa	Against Inaba
5.43	5.72